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Of Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

OREGON MEDICAL ASSOCIATION,
an Oregon not for profit corporation;
ANTON K. BROMS, MD, an individual;
and **STEWART M. WILSON, J.R., MD**,
an individual.

Plaintiffs,

v.

MICHAEL O. LEAVITT, in his official
capacity as Secretary of Health and Human
Services; **MARK B. McCLELLAN**, in
his official capacity as Administrator of
Centers for Medicare and Medicaid
Services; **UNITED STATES OF
AMERICA; UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES**; and **CENTERS
FOR MEDICARE AND MEDICAID
SERVICES**.

Defendants.

Case No.

CV'06 1871

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COMPLAINT

**Declaratory Judgment and Injunctive Relief
(28 U.S.C. § 2201 and 5 U.S.C. § 553)**

Nature of Action

1.

Plaintiffs' seek declaratory judgment and injunctive relief to prevent the Centers for Medicare and Medicaid Services (hereinafter "CMS"), and the United States Department of Health and Human Services (hereinafter "HHS") from exceeding their authority and encroaching upon the State of Oregon's police power to regulate the practice of medicine within the borders of Oregon. Defendants are enforcing an Interpretive Guideline which alters what a physician must do to obtain a patient's informed consent for certain medical care. Given effect, Defendants' definition of patient "informed consent" is contrary to Oregon law, ORS 677.097. This alteration of what Oregon has declared to be the law to be followed by physicians exceeds the authority delegated to the Secretary of Health and Human Services, violates the Social Security Act, and is unconstitutional.

Jurisdiction and Venue

2.

This Court has jurisdiction under 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346(a)(2) (civil action against the United States). A declaratory judgment action and injunctive relief are proper pursuant to 28 U.S.C. § 2201 (declaratory judgment) and 5 U.S.C. § 702 (Administrative Procedures Act).

3.

Venue is proper in this court pursuant to 28 U.S.C. § 1391(e), 28 U.S.C. § 1402(a)(1), and United States District Court for the District of Oregon Local Rule 3.4.

Parties

4.

Plaintiff Oregon Medical Association (hereinafter “OMA”) is a private association of physicians organized for the purpose of promoting professionalism, education, quality of care, and loss prevention among Oregon’s medical community. Enforcement of CMS’s Interpretative Guideline on the meaning of “informed consent” will directly impact the members of the OMA, and the OMA itself in its educational endeavors.

5.

Plaintiff Anton K. Broms, MD, is a physician licensed to practice medicine in the State of Oregon. Dr. Broms’ primary place of business is located in Tualatin, Oregon. Dr. Broms holds clinical privileges at Legacy Meridian Park located in Tualatin, Oregon.

6.

Plaintiff Stewart M. Wilson, Jr., MD, is a physician licensed to practice medicine in the State of Oregon. Dr. Wilson’s primary place of business is located in Roseburg, Oregon. Dr. Wilson holds clinical privileges at Mercy Medical Center and the local surgicenter located in Roseburg, Oregon.

7.

The United States of America is a sovereign nation, responsible for enacting, implementing, and enforcing the Social Security Act (hereinafter “SSA”) and regulations purportedly adopted under the authority of that Act. The United States Department of Health and Human Services (“HHS”) and the Centers for Medicare and Medicaid Services (“CMS”) are agencies of the United States that have the responsibility for implementing and enforcing

provisions of the SSA.

8.

Defendant Michael O. Leavitt (“Leavitt”) is the Secretary of Health and Human Services of the United States and is sued in his official capacity. Defendant Mark B. McClellan is the Administrator of CMS and is sued in his official capacity.

Oregon’s Patient Informed Consent Law

9.

Oregon’s patient informed consent law was enacted by the Oregon legislature in 1977, and has been codified as ORS 677.097. The law was amended in 1983 as provided in Oregon Laws, Chapter 486, section 8.

10.

ORS 677.097 establishes the process and procedure for a physician to obtain informed consent of a patient in Oregon. In order to obtain informed consent, Oregon physicians are required to explain in general terms the medical procedure or treatment to be undertaken; that there may be alternative procedures or methods of treatment, if any; and that there are risks, if any, in the procedure or treatment. After giving this general information the physician must ask the patient if the patient wants a more detailed explanation. If the patient requests further detail the physician shall disclose in substantial detail the procedure, the viable alternatives and the material risks unless it would be materially detrimental to the patient.

11.

An interpretive guideline adopted by CMS purports to clarify 42 C.F.R. §482.24(c)(2)(v) by setting forth a list of conditions that must be met to constitute patient informed consent for

medical treatment or surgical procedure. The SSA, and its implementing regulations, do not define for medical purposes what constitutes patient informed consent. Traditionally, that determination has been left to each State. The CMS guideline eliminates patient choice and requires additional statements not required by Oregon law.

12.

Oregon law requires that physicians obtain a patient's informed consent before providing or conducting medical treatment and/or surgical procedures. Oregon's legislature has proscribed through legislative enactment the requirements for obtaining patient "informed consent." CMS's interpretation of the definition of "informed consent" is contrary to Oregon law.

13.

By interpreting the definition of what constitutes patient "informed consent" in a manner contrary to Oregon law, CMS is attempting to exercise supervision and control over the practice of medicine and manner in which healthcare is provided in Oregon. The SSA, codified at 42 U.S.C. § 1395, specifically provides:

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

The SSA prohibits HHS, CMS, or any other Federal agency from exercising any supervision or control over the practice of medicine or manner in which medicine is provided in Oregon or any other State. Oregon has a law which governs informed consent and yet CMS's Interpretive

Guidelines seek to override Oregon law. CMS's Interpretive Guideline §482.24(c)(2)(v) provides as follows:

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§482.24(c)(2)(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

Interpretive Guidelines §482.24(c)(2)(v)

All inpatient and outpatient medical records must contain a properly executed and completed written informed consent form for all procedures and treatments specified by the hospital's medical staff, or State or Federal laws or regulations.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations, consequences, and options needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out. We recognize that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of hospital;
- Name of specific procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedures, as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Risks;
- Alternative procedures, treatments or therapies;
- Signature of patient or legal guardian;

- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

Situations where the patient consents to a procedure and information was withheld from the patient, where if the patient had been informed of that information, the patient may not have consented to the procedure or made the same decisions would not be considered informed consent

This interpretive guideline purports to clarify 42 C.F.R. §482.24(c)(2)(v) which provides:

“[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.” CMS’s own administrative regulation, 42 C.F.R. §482.24(c)(2)(v), recognizes that informed consent is proper if it is obtained in accordance with State law.

14.

As a result of Defendants’ interpretation of 42 C.F.R. §482.24(c)(2)(v) as provided in CMS’s State Operations Manual, Oregon physicians who obtain patient informed consent for medical treatment or surgical procedures in conformance with Oregon law are subject to disciplinary proceedings by healthcare facilities resulting in revocation of physician clinical privileges; and reporting to the National Practitioners Data Bank. Defendants have stated their intent to sanction healthcare facilities who participate in the Medicare and Medicaid programs, if such facilities allow physicians to provide medical treatment or surgical procedures without the physician obtaining and documenting patient informed consent as prescribed by CMS’s interpretive guidelines regardless of whether patient informed consent was obtained in

accordance with Oregon law.

15.

Legacy Health System hospitals are healthcare facilities organized as an Oregon not for profit corporation. Legacy Meridian Park Hospital is a part of the Legacy Health System. Legacy Meridian Park Hospital participates in the Medicare and Medicaid programs. Legacy Meridian Park Hospital's participation in the Medicare and Medicaid programs is subject to the provisions of the SSA and the administrative regulations adopted to implement the Medicare and Medicaid programs created by the SSA.

16.

As the result of an audit conducted by the Oregon Department of Human Services, on behalf of CMS, the Legacy Health System hospitals have been notified by CMS, that unless they require physicians to document informed consent as prescribed by CMS's interpretive guidelines, the Legacy Health System hospitals will be terminated from the Medicare and Medicaid programs.

17.

Plaintiff Broms, MD, and other physicians with clinical privileges at Legacy Health System hospitals have been told by the administrative department of Legacy Health System that they must comply with CMS's interpretative guidelines defining patient "informed consent" for all medical treatment or surgical procedures performed or delivered to patients at Legacy Health System hospitals or else their clinical privileges will be revoked.

18.

Mercy Medical Center is a healthcare facility organized as an Oregon not for profit corporation. Mercy Medical Center participates in the Medicare and Medicaid programs. Mercy Medical Center's participation in the Medicare and Medicaid programs is subject to the provisions of the SSA and the administrative regulations adopted to implement the Medicare and Medicaid programs created by the SSA.

19.

As the result of an audit conducted by the Oregon Department of Human Services, on behalf of CMS, Mercy Medical Center has been notified by CMS, that unless it requires physicians to document informed consent as prescribed by CMS's interpretive guidelines, Mercy Medical Center will be terminated from the Medicare and Medicaid programs.

20.

Plaintiff Wilson, MD, and other physicians with clinical privilege at Mercy Medical Center have been told by the administrative department of Mercy Medical Center that they must comply with CMS's interpretative guideline defining patient "informed consent" for all medical treatment or surgical procedures performed or delivered to patients at Mercy Medical Center.

Claim for Relief
(Declaratory Judgment and Injunctive Relief)

21.

Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-20 above.

22.

Plaintiffs contend that CMS's interpretive guideline defining patient "informed consent" as that term is used in 42 C.F.R. §482.24(c)(2)(v) violates the rule making requirements of the Administrative Procedures Act (APA), 5 U.S.C. § 553; violates the rule making requirement of 42 U.S.C. §1395hh; violates the express prohibition that no Federal officer or employee may exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, 42 U.S.C. § 1395; and violates the Tenth Amendment of the United States Constitution by usurping powers the Constitution denies to Congress and reserves to the states or the people.

23.

Defendants contend that Interpretative Guideline §482.24(c)(2)(v) and its enforcement is valid and permissible, and are enforcing it.

24.

Plaintiffs have a present need to know whether Interpretative Guideline §482.24(c)(2)(v) and its enforcement is valid.

25.

There is a present justiciable controversy between the parties as to whether Interpretative Guideline §482.24(c)(2)(v) and its enforcement is valid. Declaratory relief is appropriate to resolve this controversy.

26.

Plaintiffs ask this court to declare that Interpretative Guideline §482.24(c)(2)(v) contained in CMS's State Operations Manual and its enforcement violates the SSA; the APA; and the United States Constitution.

27.

Plaintiffs ask this court to preliminarily and permanently enjoin Defendants from enforcing or otherwise giving effect to Interpretative Guideline §482.24(c)(2)(v) contained in CMS's State Operations Manual.

28.

Pursuant to 28 U.S.C. §§ 1920 and 2412 (a)(1), Plaintiffs are entitled to recover their costs of suit. Pursuant to 28 U.S.C. § 2412(b) and (d)(1)(A), Plaintiffs are entitled to recover reasonable attorney fees incurred in connection with this litigation.

WHEREFORE, Plaintiffs request entry of judgment in their favor as follows:

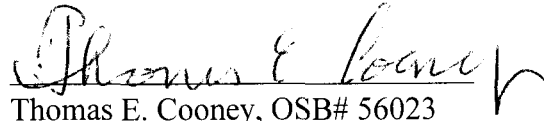
1. Declaring Interpretative Guideline §482.24(c)(2)(v) contained in CMS's State Operations Manual invalid;
2. Declaring enforcement of Interpretative Guideline §482.24(c)(2)(v) contained in CMS's State Operations Manual exceeds the authority of Defendants or is unconstitutional;
3. Preliminarily and permanently enjoining Defendants from enforcing or otherwise giving effect to interpretative guideline §482.24(c)(2)(v) contained in CMS's State

Operation Manual;

4. Awarding Plaintiffs their reasonable attorney fees and costs of suit; and
5. Awarding Plaintiffs such other relief as the court deems equitable and just.

DATED this 28th day of December, 2006.

COONEY & CREW, LLP

A handwritten signature in cursive script, appearing to read "Thomas E. Cooney", written over a horizontal line.

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